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DRAFT

State Water Resources Control Board
Division of Drinking Water
Environmental Laboratory Accreditation Program

Accreditation of Environmental Laboratories

Title 22. Social Security

Division 4. Environmental Health

Chapter 19. Certification of Environmental Laboratories

Article 1. Definitions.

Amend Section 64801 to read as follows:

§ 64801. Definitions.

The relevant definitions listed in the 2016 TNI Standard, Volume 1 apply throughout this regulation except as otherwise defined in this section.

~~(a) "Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the method(s) cited in Section 64811(a), (b), or (c), but detects and quantifies to the same degree of precision, accuracy, and level of detection.~~

(a) "Acceptable Scores" means analytical results for a Proficiency Testing sample are within the specified acceptance criteria for that sample.

~~(b) "Auxiliary Laboratory Facility" means any stationary place which:~~

~~(1) is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and~~

~~(2) performs analyses in one or more of the same auxiliary; and Field(s) of Testing as the laboratory to which it is auxiliary; and~~

~~(3) is under the supervision of the same Laboratory Director as the laboratory to which it is auxiliary; and~~

~~(4) only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and~~

~~(5) is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.~~

(b) “Accreditation” means the recognition of a laboratory by the State Board to conduct analyses of environmental samples for regulatory purposes.

~~(c) “A Complete Application” means a verified application for certification containing all the information required in Section 64805(a) or (b), and utilizing ELAP form 001 (dated 1/1/93).~~

(c) “Assessment Firm” means a private company that is approved by the State Board to conduct laboratory assessments for the State Board.

~~(d) “Contact Person” means an individual designated by the Laboratory Director to act as a contact between the laboratory and the Department for purposes of exchanging information between the Department and the laboratory.~~

(d) “California Analyte” means a substance, organism, physical parameter, property, or chemical constituent(s) regulated in California.

~~(e) “Laboratory” shall have the same meaning as given in Health and Safety Code Section 1010(e)(2).~~

(e) “A Completed Application Package” means the State Board has received an application package for accreditation and the application package contains all the information required in Section 64802.05.

~~(f) “Laboratory Director” means the person who, for the laboratory and its auxiliary or mobile laboratories, if any, is in charge of all analytical and operational laboratory activities; supervises all personnel, including those designated as Principal Analysts; and is the person responsible for the quality of reported data.~~

(f) “Days” means calendar days, unless otherwise indicated.

~~(g) “Facility or Facilities” means fixed or portable building(s), which contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the Field(s) of Testing for which a laboratory is certified accredited, and includes storage areas.~~

(g) “Denial” means a decision by the State Board to reject an application for accreditation due to not meeting the accreditation criteria in accordance with Section 64802.00.

~~(h) “Mobile Laboratory” means a vehicle, vessel, aircraft, or trailer, which is certified under Field of Testing 23, and is operated by the same owner as a certified stationary laboratory, and which is designed and equipped for the purpose of transporting and using laboratory equipment to perform analyses in one of the Fields of Testing for which the stationary laboratory is certified.~~

(h) "Deviations" are ways in which a laboratory is not in compliance with applicable laws and regulations.

~~(i) "Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.~~

(i) "ELAP" means the California Environmental Laboratory Accreditation Program.

~~(j) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.~~

(j) "Field of Accreditation" means a testing category identifying Units of Accreditation offered for accreditation.

~~(k) "Principal Analyst" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments. For these purposes, "sophisticated laboratory instruments" means: gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), direct current plasma spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), or high pressure liquid chromatographs (HPLC).~~

(k) "Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

~~(l) "Stationary Laboratory" means a laboratory that is permanent and nonmovable and may include fixed-in-place vehicles.~~

(l) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.

~~(m) "Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.~~

(m) "Primary Accreditation Body" means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, documents, PT sample results, and onsite assessments.

~~(n) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.~~

(n) "Sophisticated Instrument" means analytical instrumentation such as gas chromatograph/mass spectrometer (GC/MS), ion chromatography (IC), inductively coupled plasma spectrometer (ICP), inductively coupled plasma/mass spectrometer (ICP/MS), liquid chromatograph/mass spectrometers (LC/MS), atomic absorption spectrophotometer (AA), gas chromatograph (GC), alpha particle or gamma ray spectrophotometer, electron microscope (EM), polarized light microscope (PLM), high pressure liquid chromatograph (HPLC), or other similar instrument including use of aquatic organisms in toxicity testing of wastewater and hazardous waste.

~~(o) "Utility-Owned" means laboratories owned and operated by federal, state, city, or county agencies.~~

(o) "State Board" means the California State Water Resources Control Board.

~~(p) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.~~

(q) "TNI" means The National Environmental Laboratory Accreditation Conference Institute.

(r) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.

~~(q) "Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner.~~

(s) "Unit of Accreditation" means a component of the Field of Accreditation, including (a) the matrix, (b), a test method or technology, and (c) a designated analyte or designated group of analytes. The Unit of Accreditation is specific to testing (e.g., the matrix, the method, and the analyte or group of analytes) for an individual regulatory requirement, such as is needed for compliance with the Safe Drinking Water Act or the Clean Water Act, or for specific agency requirements, such as those established by the Department of Toxic Substances Control or the Department of Food and Agriculture.

(t) "Vessel" includes ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place for the transportation of merchandise or persons. This definition is the same as given in

Section 21, Harbors and Navigation Code.

Note: Authority cited: ~~Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1010, 1014 and 1017, Health and Safety Code; Section 6254.7(d), Government Code; Sections 630 and 670, Vehicle Code; Section 21, Harbors and Navigation Code.~~

Amend Title of Article 2 to read as follows:

Article 2. ~~Certification and Amendment Process~~ Accreditation Requirements.

Adopt Section 64802.00 to read as follows:

§64802.00 General Accreditation Criteria.

- (a) To obtain accreditation, a laboratory and its auxiliary laboratory, or a mobile laboratory shall:
- (1) Submit a completed application package, in accordance with Section 64802.05;
 - (2) Comply with quality systems requirements, in accordance with Section 64802.10;
 - (3) Achieve acceptable Proficiency Testing scores for each Field(s) of Accreditation or Unit(s) of Accreditation for which accreditation is requested, in accordance with Section 64802.20;
 - (4) When required, complete an on-site assessment in accordance with Section 64802.25; and
 - (5) Pay the required fees, in accordance with Section 64802.30.
- (b) The period of accreditation shall be as follows:
- (1) For initial and renewal accreditation, 24 months;
 - (2) For amended accreditation, the time remaining on the certificate from the date it was amended;
 - (3) For reciprocity accreditation, the time remaining on the certificate provided by the primary accreditation body;
 - (4) For interim accreditation, until accreditation is either granted or denied, but no later than 12 months after the date of issuance.
- (c) To add or remove one or more Field(s) of Accreditation and/or Unit(s) of Accreditation from its certificate:
- (1) In between renewals, the laboratory shall submit an amendment application to the State Board and receive an amended certificate, in accordance with Section 64808.10;
 - (2) At the time of renewal, the laboratory shall indicate the requested changes on its renewal application.

Note: Authority cited:

Adopt Section 64802.05 to read as follows:

§64802.05. Application.

- (a) A laboratory applying for initial or renewal accreditation shall file a complete application package in a manner prescribed by the State Board, containing:
- (1) Application forms prescribed by the State Board and located on the ELAP website that includes, but is not limited to:
 - (A) Name of the laboratory;
 - (B) Details on the laboratory's type, size, location, contact information, ownership, and regulatory agencies;
 - (C) Technical manager and quality manager qualifications;
 - (D) Agreement to comply with applicable California statutes and regulations; and
 - (E) Signature of the laboratory owner, owner's agent, or officer, and date signed.
 - (2) A copy of the laboratory quality manual meeting the requirements of:
 - (A) 2016 TNI Standard Volume 1, Module 2, Section 4.2.8.3 and 4.2.8.4; or
 - (B) If a laboratory chooses to delay implementation of 2016 TNI Standard, Volume 1, the laboratory shall submit a copy of the laboratory quality manual meeting the requirements of Section 64802.10(d)(1)(A).
 - (3) Field(s) of Accreditation tables prescribed by the State Board, identifying the Unit(s) of Accreditation for which accreditation is being requested;
 - (4) Proficiency Testing report(s) with acceptable scores for each Unit(s) of Accreditation for which accreditation is requested, where Proficiency Testing studies exist; and
 - (5) Confirmation of State Board accreditation fee payment.
- (b) A laboratory applying for accreditation by reciprocity shall file a completed application package containing:
- (1) Application forms prescribed by the State Board that includes, but is not limited to:
 - (A) Name of the laboratory;
 - (B) Details on the laboratory's type, size, location, contact information and ownership;
 - (C) Technical manager and quality manager qualifications; and
 - (D) Signature of the laboratory owner, owner's agent, or officer, and date signed.
 - (2) A copy of the laboratory quality manual;
 - (3) Field(s) of Accreditation tables prescribed by the State Board, identifying the Unit(s) of Accreditation for which accreditation is being requested;
 - (4) Proficiency Testing report(s) with acceptable scores for each Unit of Accreditation for which accreditation is requested, where Proficiency Testing studies exist;
 - (5) Proof of accreditation from a primary accreditation body, including:
 - (A) Official certificate and Scope of Accreditation;
 - (B) Official On-Site Assessment Report and findings;

- (C) Corrective action plan(s) reviewed and approved by the primary accreditation body; and
- (6) Confirmation of State Board accreditation fee payment.

- (c) If an application for initial accreditation does not contain the requirements of (a), within 30 days of receipt by the State Board the laboratory will be notified and the application will become inactive. Any noted deviations shall be corrected and the corrected application returned to the State Board to continue processing of the application.
- (d) If an application for renewal accreditation does not meet the requirements of (a), within 30 days of receipt by the State Board, the laboratory will be notified. Any noted deviations shall be corrected and the corrected application returned to the State Board within 15 days from the date of the State Board's notice or the application shall be considered null and void.
- (e) If an application for reciprocity accreditation does not meet the requirements of (b), within 30 days of receipt by the State Board the laboratory will be notified and the application will become inactive. Any noted deviations shall be corrected and the corrected application returned to the State Board to continue processing of the application.
- (f) Beginning September 1, 2020 all application packages shall be due 90 days prior to September 1, of each year.

Note: Authority cited:

Adopt Section 64802.10 to read as follows:

§64802.10. Quality Systems.

- (a) To obtain accreditation, a laboratory shall comply with the management and technical requirements applicable to their operations in accordance with 2016 TNI Standard Volume 1, Module 2 – 7, with the following exceptions:
 - (1) Volume 1, Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications;
and
 - (2) Volume 1, Module 2, Section 5.2.6 – Additional Personnel Requirements.
- (b) The management and technical requirements in (a) will become operative January 1, 2022.
- (c) Laboratories voluntarily choosing to implement the management and technical requirements in (a) prior to January 1, 2022, upon review and approval by the State Board, shall:
 - (1) Be granted priority accreditation upon submittal of written notification that includes:
 - (A) A statement asserting compliance with (a);

- (B) An acceptable On-Site Assessment Report including applicable Corrective Action Report from an approved laboratory assessment firm demonstrating compliance with (a).
 - (2) Comply with all provisions of these regulations, including the management and technical requirements in (a) upon receipt of accreditation.
 - (3) Accreditation shall be granted retroactively to the date of receipt of notification by the State Board.
- (d) A laboratory that has not implemented the management and technical requirements in (a) prior to January 1, 2022 shall:
- (1) Develop and implement a quality assurance program to ensure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality manual.
 - (A) The quality manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The quality manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.
 - (B) The technical manager shall review, and amend if necessary, the quality assurance program and quality manual at least annually. The technical manager shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.
 - (C) A laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for a minimum of five years.
 - (2) Submit quarterly quality assurance reports to the State Board documenting compliance with subsection (1), including corrective actions for any noted deviations.
 - (3) This subsection will become inoperative January 1, 2022.

Note: Authority cited:

Adopt Section 64802.15 to read as follows:

§64802.15. Field(s) of Accreditation.

- (a) The State Water Board will accredit laboratories for Field(s) of Accreditation and Unit(s) of Accreditation that are required by state agencies that require environmental analysis for regulatory purposes. Those Fields and Units of Accreditation will be identified by ELAP on its website, and updated, as necessary, to accommodate state agency regulatory needs.

Note: Authority cited:

Adopt Section 64802.20 to read as follows:

§64802.20. Proficiency Testing.

- (a) A laboratory shall comply with the requirements for accreditation in accordance with 2016 TNI Standard, Volume 1, Module 1 for each Unit of Accreditation for which the laboratory is requesting accreditation and where corresponding Proficiency Testing studies exist, with the following exceptions:
- (1) Volume 1, Module 1, Section 5.0 – Proficiency Testing Study Frequency Requirements for Accreditation;
 - (2) Volume 1, Module 1, Section 8.0 – Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation;
- (b) To obtain initial accreditation, at least 90 days prior to the State Board’s receipt of the laboratory’s application a laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for each Unit of Accreditation on its application where corresponding Proficiency Testing studies exist.
- (c) To maintain accreditation, one year from the effective date on the laboratory’s State Board certificate, a laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for each Unit of Accreditation for which a laboratory holds accreditation and which a Proficiency Testing study exists.
- (1) If a laboratory does not achieve acceptable scores for a Unit of Accreditation, within 7 calendar days upon receipt of the “Not Acceptable” results from the Proficiency Testing provider a laboratory shall:
 - (A) Determine the root cause of the failure and take corrective action.
 - (i) The laboratory shall provide the root cause investigation and corrective action documentation to the State Board within 30 calendar days of a request from the State Board;
 - (B) Achieve acceptable scores in a subsequent Proficiency Testing study for the Unit of Accreditation and submit a Proficiency Testing report(s) to the State Board with acceptable scores for that Unit of Accreditation.
 - (2) If a laboratory does not achieve acceptable scores for a Unit of Accreditation in two consecutive Proficiency Testing studies, a laboratory shall:
 - (A) Notify the State Board, and have its accreditation for that Unit of Accreditation suspended effective upon receipt of the second “Not Acceptable” results from the Proficiency Testing provider;

- (B) Cease all analytical work for regulatory purposes for that Unit of Accreditation effective upon receipt of the second “Not Acceptable” results from the Proficiency Testing provider; and
 - (C) Determine the root cause of the failure and take corrective action.
 - (i) The laboratory shall provide the root cause investigation and corrective action documentation to the State Board within 30 calendar days of a request from the State Board;
 - (D) To be reinstated after suspension of a Unit of Accreditation the laboratory shall achieve an acceptable score in a Proficiency Testing study for the Unit of Accreditation and submit a Proficiency Testing report(s) to the State Board with acceptable scores for that Unit of Accreditation.
- (d) For renewals, 90 days prior to the State Board’s receipt of the laboratory’s renewal application, a laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for each Unit of Accreditation for which a Proficiency Testing study exists.
- (1) If a laboratory does not achieve acceptable scores for a Unit of Accreditation, within 7 calendar days upon receipt of the “Not Acceptable” results from the Proficiency Testing provider a laboratory shall:
 - (A) Determine the root cause of the failure and take corrective action.
 - (i) The laboratory shall provide the root cause investigation and corrective action documentation to the State Board within 30 calendar days of a request from the State Board;
 - (B) Achieve acceptable scores in a subsequent Proficiency Testing study for the Unit of Accreditation and submit a Proficiency Testing report(s) to the State Board with acceptable scores for that Unit of Accreditation.
 - (2) If a laboratory does not achieve acceptable scores for a Unit of Accreditation in two consecutive Proficiency Testing studies, a laboratory shall:
 - (A) Notify the State Board, and have its accreditation for that Unit of Accreditation suspended effective upon receipt of the second “Not Acceptable” results from the Proficiency Testing provider;
 - (B) Cease all analytical work for regulatory purposes for that Unit of Accreditation effective upon receipt of the second “Not Acceptable” results from the Proficiency Testing provider; and
 - (C) Determine the root cause of the failure and take corrective action.
 - (i) The laboratory shall provide the root cause investigation and corrective action documentation to the State Board within 30 calendar days of a request from the State Board;
 - (D) To be reinstated after suspension of a Unit of Accreditation the laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for the Unit of Accreditation and submit a Proficiency Testing report(s) to the State Board with acceptable scores for that Unit of Accreditation.
- (e) For toxicity bioassay in any Field of Accreditation, each laboratory shall:

- (1) Achieve acceptable scores in Proficiency Testing studies, where Proficiency Testing studies exist;
 - (2) Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and
 - (3) Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint.
- (f) For pesticide residue in food in any Field(s) of Accreditation, each laboratory shall participate in Proficiency Testing studies approved by the State Board.
- (g) For a California analyte for which there is no commercial Proficiency Testing study available that meets the requirements in Subsection (a), the State Board may require an alternative demonstration of proficiency.
- (h) If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a Proficiency Testing study, the results from that study shall not be used to meet the Proficiency Testing study requirements for accreditation.

Note: Authority cited:

Adopt Section 64802.25 to read as follows:

§64802.25. On-Site Assessment.

- (a) A laboratory shall be subject to an on-site assessment to verify the information submitted with its State Board application, and compliance with:
- (1) Management and technical requirements in accordance with Section 64802.10; and
 - (2) Analytical methods used for each Unit of Accreditation for which the laboratory seeks accreditation.
- (b) A laboratory that has not implemented the management and technical requirements applicable to their operations in accordance with 2016 TNI Standard Volume 1, Module 2-7 prior to January 1, 2022 in accordance with Section 64802.10, shall be subject to an on-site assessment to verify the information submitted with its State Board application, and compliance with:
- (1) The laboratory's quality assurance and quality control procedures in accordance with Section 64802.10(d)(1)(A);
 - (2) The laboratory's instrumentation and equipment requirements in Section 64812.05(c); and
 - (3) Analytical methods used for each Unit of Accreditation for which the laboratory seeks accreditation.
- (c) When an on-site assessment is performed by the State Board a laboratory shall pay an assessment fee in accordance with Section 64802.30.

- (d) If any deviations are noted, within 30 days of the on-site assessment the laboratory will receive an On-Site Assessment Report.
- (1) Within 30 days of receipt of the On-Site Assessment Report, the laboratory shall submit a Corrective Action Report that details how each identified deviation has been investigated and corrections initiated and completed; the laboratory will be notified within 30 days whether the Corrective Action Report demonstrates the corrections.
 - (2) If the laboratory is notified that the Corrective Action Report does not adequately address the identified deviations, the laboratory shall have an additional 30 days from its receipt of the notification to submit a revised Corrective Action Report; if the revised report still does not demonstrate the required corrections, accreditation shall be denied, suspended or revoked for any Field(s) of Accreditation and/or Unit(s) of Accreditation affected by failure to take corrective action.
 - (3) If in a subsequent on-site assessment, either announced or unannounced, the State Board determines that the laboratory failed to take any of the corrective action(s) specified by the laboratory, accreditation shall be denied, suspended, or revoked for any Field(s) of Accreditation and/or Unit(s) of Accreditation affected by failure to take corrective action.
- (e) If an on-site assessment is not conducted within 6 months from the date a laboratory's application is received by the State Board, and the delay is not a result of State Board error or procedure, unless otherwise approved by the State Board accreditation shall be denied, suspended or revoked.

Note: Authority cited:

Adopt Section 64802.30 to read as follows:

§64802.30. Accreditation Fees (PLACE HOLDER).

Note: Authority cited:

Repeal Section 64803

~~§64803. Certification and Amendment.~~

~~(a) A laboratory and its auxiliary or mobile laboratories shall be certified for a 24 month period in the Subgroups within each Field of Testing applied for when all the following have occurred:~~

- ~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation sample study sets have been received by the Department pursuant to Section 64809; and~~

~~(4) payment of the basic fee and per-Field-of-Testing fees published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) has been made to the Department.~~

~~(b) A laboratory desiring to add or remove one or more Subgroups within a Field(s) of Testing from its current certificate shall file a written request detailing the Field(s) of Testing or Subgroup(s) to be added or removed. Additions, which shall be effective for the remainder of the certification period, shall be made, and an amended certificate issued, when all of the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation samples have been received by the Department pursuant to Section 64809; and~~

~~(4) payment for a per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Sections 113 and 1017(a) for each Field of Testing to be added to the certificate has been made to the Department.~~

~~(c) Whenever there is an amendment to a certificate, the certificate number and the expiration date on the amended certificate shall be the same as the original certificate.~~

~~(d) Laboratories seeking an amendment to add one or more Subgroups within a Field(s) of Testing shall not perform analyses in the additional Field(s) of Testing, or Subgroup(s) of Field(s) of Testing, until approved by the Department as evidenced by the issuance of an amended certificate.~~

~~(e) Laboratories seeking removal of one or more Subgroups within a Field(s) of Testing shall not perform analyses in the Field of Testing, or Subgroup, after the date of its written request for removal.~~

~~(f) A laboratory desiring interim certification under authority of Health and Safety Code, Section 1015(d) shall file a written request for interim certification with its application. An interim certificate shall be issued after payment of the basic and per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) for each Field of Testing applied for, completion of the requirements of either Section 64807 or 64809, and after the Department has determined that the laboratory~~

~~has submitted a complete application. In cases where reciprocity agreements exist, compliance with Section 64807 shall be based on a site visit report issued by the other government agency and conducted within 6 months prior to the request for interim certification.~~

~~(g) The Department's estimated schedule for processing a complete application for certification from the receipt of the complete application to the final decision regarding issuance or denial of a certificate is as follows:~~

- ~~(1) The median time is 6 months;~~
- ~~(2) The minimum time is 3 months;~~
- ~~(3) The maximum time is 12 months.~~

~~— Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 113, 1012, 1013, 1014 and 1015, Health and Safety Code.~~

Amend Title of Article 3.

Article 3. ~~Application Process~~. Types of Accreditation.

Repeal Section 64805.

~~§64805. Application.~~

~~(a) All laboratories seeking certification in any Subgroup as identified in Section 64823 within Field(s) of Testing 1 through 22, as listed in Health and Safety Code, Section 1017, shall file a complete application utilizing ELAP form 001, dated January 1, 1993, and containing the following information:~~

- ~~(1) complete name of the laboratory; and~~
- ~~(2) if the laboratory is stationary, the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the laboratory and any auxiliary laboratories; and~~
- ~~(3) if the laboratory is owned by a holder of a waste discharge permit issued by a California Regional Water Quality Control Board, the name or number of the Regional Board issuing the permit; and~~
- ~~(4) mailing address, parcel or package delivery address of the laboratory and any auxiliary laboratories; and~~
- ~~(5) if the laboratory is a vehicle or trailer, the vehicle identification and license plate number, including state of issue, or if the laboratory is a vessel, the vessel~~

~~identification number, vessel registration number, including state of issue, or if the laboratory is an aircraft, the aircraft identification number, aircraft registration number, including state of issue, of all mobile laboratories; and~~

~~(6) name, education, and experience for the person designated as the Laboratory Director; and~~

~~(7) name, education, and experience for each and every person designated as Principal Analyst; and~~

~~(8) name of a Contact Person; and~~

~~(9) phone numbers for the laboratory, fax devices, Laboratory Director, and Contact Person; and~~

~~(10) the name(s) of the Owner(s) of the laboratory. If the laboratory is owned by a corporation, the name of the officers, and stockholders owning 5% or more of the shares. If the laboratory is owned by a partnership, the name of all partners; and~~

~~(11) whether the laboratory seeks exemption from fees as allowed by Health and Safety Code, Section 1017(e). If exemption is claimed, it shall include evidences showing the laboratory to be established under the authority of Health and Safety Code, Section 1000, or that the laboratory meets the definition of a government-owned reference laboratory as established in Health and Safety Code, Section 1017(g); and~~

~~(12) the Field(s) of Testing for which the laboratory desires certification; and~~

~~(13) a quality assurance document meeting the requirements of Section 64815; and~~

~~(14) date of completion of the application and signature by an Owner.~~

~~(b) Laboratories seeking certification of a mobile laboratory under Field of Testing 23, shall file a complete application, which shall include the following information:~~

~~(1) the Subgroup within the Field of Testing to be employed in the mobile laboratory; and~~

~~(2) the name of the Owner(s) of the stationary laboratory that operates the mobile laboratory; and~~

~~(3) name, education, and experience for the person designated as Laboratory Director for the stationary laboratory that operates the mobile laboratory; and~~

~~(4) name, education and experience for each and every person designated as Principal Analyst for the mobile laboratory; and~~

~~(5) a quality assurance program meeting the requirements of Section 64815 covering the test methods to be employed in the mobile laboratory; and~~

~~(6) the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the certified stationary laboratory under the same owner as the mobile laboratory and the Subgroups within each Field of Testing for which that stationary laboratory is certified.~~

~~(c) All applications filed with the Department shall be considered complete unless within 30 days of receipt, the Department mails to the laboratory's mailing address a notice that the application is not complete. Any noted deficiencies in a submitted application must be corrected and the corrected application returned to the Department within ninety days from the date of the Department's notice of deficiencies or the application shall be considered null and void.~~

~~(d) An application for renewal of a certificate shall be received by the Department no later than ninety days prior to the expiration date of the certificate or it shall expire by operation of law on the stated expiration date as specified in Health and Safety Code Section 1014(a).~~

~~—Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1013, 1014 and 1017(e), Health and Safety Code.~~

Adopt Section 64808.00 to read as follows:

§64808.00 Initial Accreditation.

(a) To obtain initial accreditation, a laboratory shall:

- (1) Submit a completed application package in accordance with Section 64802.05;
- (2) Comply with management and technical requirements, in accordance with Section 64802.10;
- (3) Be subject to an on-site assessment and comply with Section 64802.25; and
- (4) Pay the required fees, in accordance with Section 64802.30.

Note: Authority cited:

Adopt Section 64808.05 to read as follows:

§64808.05 Renewal Accreditation.

(a) To renew accreditation, a laboratory shall:

- (1) At least 90 days prior to its certificate expiration date, submit a renewal application in accordance with Section 64802.05.

- (A) A renewal application submitted prior to the certificate expiration date, but less than 90 days prior to that date, may result in expiration of the certificate on the stated expiration date, in accordance with Health and Safety Code Section 100845. On the certificate expiration date the laboratory shall cease all reporting of analytical work for regulatory purposes, and notify clients of its lapse in accreditation by registered mail. To renew accreditation the laboratory shall be subject to:
 - (i) A late fee equal to 15% of its accreditation fee in addition to the accreditation fee; and
 - (ii) A gap in accreditation to account for processing of the late application.
- (B) If a laboratory does not submit its renewal application by the certificate expiration date, as of that date, the laboratory shall cease all reporting of analytical work for regulatory purposes, and notify clients of its lapse in accreditation. To renew accreditation the laboratory shall be subject to:
 - (i) A late fee equal to 30% of its accreditation fee in addition to the accreditation fee; and
 - (ii) A gap in accreditation to account for processing of the late application.
- (C) If a laboratory fails to submit its renewal application by 90 days after its certificate expiration date, accreditation shall not be renewable.
 - (i) To obtain accreditation, the laboratory shall be required to apply as for an initial accreditation, pursuant to Section 64808.00.
- (2) Comply with management and technical requirements, in accordance with Section 64802.10;
- (3) Within a three year interval, be subject to an on-site assessment and comply with Section 64802.25; and
- (4) Pay the required fees, in accordance with Section 64802.30.

Note: Authority cited:

Adopt Section 64808.10 to read as follows:

§64808.10 Amendment Accreditation.

- (a) To amend accreditation for the following reasons, a laboratory shall file the appropriate application and pay the fee in accordance with Section 64802.30:
 - (1) Change its name, except that if the name is changed in connection with a sale or transfer of ownership, then the laboratory shall comply with Section 64814.05;
 - (2) Change its location;
 - (3) Add an auxiliary laboratory; and
 - (4) Modify the Field(s) of Accreditation and Unit(s) of Accreditation for which it is accredited.

- (b) A laboratory applying to change its name shall:
- (1) File an application on forms prescribed by the State Board that requires the following:
 - (A) Existing name of the laboratory;
 - (B) Certificate number of the laboratory;
 - (C) Address of the laboratory;
 - (D) Proposed new name of the laboratory; and
 - (E) Signature of the laboratory owner, owner's agent, or officer, and date signed.
 - (2) Pay the fee in accordance with Section 64802.30.
- (c) A laboratory applying for a change of location shall:
- (1) Within 30 days before the change of location, file an application on forms prescribed by the State Board that provides, at a minimum, the following:
 - (A) Name of the laboratory;
 - (B) Certificate number of the laboratory;
 - (C) Existing or previous address of the laboratory;
 - (D) New address of the laboratory;
 - (E) Description of the new location; and
 - (F) Signature of the laboratory owner, owner's agent, or officer, and date signed.
 - (2) The laboratories accreditation shall be suspended on the last day of operation at the old location, all work for regulatory compliance shall cease, and clients shall be notified of the suspended status.
 - (3) To be reinstated, a laboratory shall:
 - (A) Submit updates to the quality manual that are necessary because of the change of location;
 - (B) Submit any new or revised Standard Operating Procedure(s) necessitated by the change of location;
 - (C) Where applicable, comply with:
 - (i) For Asbestos testing, 2016 TNI Standard, Volume 1, Module 3;
 - (ii) For Chemical testing, 2016 TNI Standard, Volume 1, Module 4;
 - (iii) For Microbiological testing, 2016 TNI Standard, Volume 1, Module 5;
 - (iv) For Radiochemistry testing, 2016 TNI Standard, Volume 1, Module 6; and
 - (v) For Toxicity testing, 2016 TNI Standard, Volume 1, Module 7.
 - (D) Submit Proficiency Testing report(s) with acceptable scores for all Unit(s) of Accreditation for which the laboratory is requesting accreditation, where Proficiency Testing studies exist; and
 - (E) If at the State Board's discretion an on-site assessment is conducted,

- the laboratory shall comply with Section 64802.25.
- (4) Pay the fee in accordance with Section 64802.30.
- (d) A laboratory applying to add an auxiliary laboratory(s) shall:
- (1) Prior to applying, ensure the auxiliary laboratory(s) meets the criteria for an auxiliary laboratory set forth in Section 64810.05(b);
 - (2) File an application on forms prescribed by the State Board that require, at a minimum:
 - (A) Name of the laboratory;
 - (B) Details on the laboratory's type, size, location, contact information and ownership;
 - (C) Technical manager and quality manager qualifications;
 - (D) Agreement to comply with applicable California statutes and regulations; and
 - (E) Signature of the laboratory owner, owner's agent, or officer, and date signed;
 - (3) Submit the Field(s) of Accreditation on forms prescribed by the State Board, identifying the Unit(s) of Accreditation for which the auxiliary laboratory is requesting accreditation;
 - (4) Submit Proficiency Testing report(s) with acceptable scores for each Unit(s) of Accreditation for which the auxiliary laboratory is requesting accreditation, where Proficiency Testing studies exist;
 - (5) If at the State Board's discretion an on-site assessment is conducted, the auxiliary laboratory shall comply with Section 64802.25; and
 - (6) Pay the fee in accordance with Section 64802.30.
- (e) A laboratory applying to add a Field(s) of Testing and/or Unit(s) of Accreditation shall:
- (1) File an application on forms prescribed by the State Board that require, at a minimum:
 - (A) Name of the laboratory;
 - (B) Certificate number of the laboratory; and
 - (C) Address of the laboratory;
 - (2) Submit Field(s) of Accreditation tables prescribed by the State Board, identifying the Unit(s) of Accreditation for which accreditation is being amended;
 - (3) Submit any portion of the quality manual that differs relating to the proposed amendment from the version of the quality manual most recently submitted to the State Board;
 - (4) Provide the State Board with information necessary for the State Board to determine whether the laboratory has the capability to conduct the analysis for each Field of Accreditation and Unit of Accreditation for which the

amended accreditation is requested. This information shall include, but not be limited to:

- (A) Documentation that the laboratory has the necessary equipment and instrumentation;
 - (B) Submit any new or revised Standard Operating Procedure(s) that pertain to the additional Fields or Units of Accreditation;
 - (C) Where applicable, comply with:
 - (i) For Asbestos testing, 2016 TNI Standard, Volume 1, Module 3;
 - (ii) For Chemical testing, 2016 TNI Standard, Volume 1, Module 4;
 - (iii) For Microbiological testing, 2016 TNI Standard, Volume 1, Module 5;
 - (iv) For Radiochemistry testing, 2016 TNI Standard, Volume 1, Module 6; and
 - (v) For Toxicity testing, 2016 TNI Standard, Volume 1, Module 7
 - (5) Submit Proficiency Testing report(s) with acceptable scores for all Unit(s) of Accreditation for which the laboratory is requesting accreditation, where Proficiency Testing studies exist;
 - (6) If at the State Board's discretion an on-site assessment is conducted, the laboratory shall comply with Section 64802.25; and
 - (7) Pay the fee in accordance with Section 64802.30.
- (f) A laboratory is not required to file an application for amended accreditation to remove a Field of Testing and/or Unit of Accreditation, but may request an amended certificate to remove a Field of Testing and Unit of Accreditation by submitting a written request to the State Board.

Note: Authority cited:

Adopt Section 64808.15 to read as follows:

§64808.15 Interim Accreditation.

- (a) If a laboratory has submitted a completed application in accordance with Section 64802.05, and additional time is needed by the State Board to complete an on-site assessment, the laboratory shall be issued interim accreditation.
- (b) Interim accreditation is not renewable and shall be valid until:
 - (1) An on-site assessment has been completed and an amended certificate issued;
 - (2) The laboratory fails to meet the requirements for accreditation in accordance with Section 64802.25; or
 - (3) The end of one year from its issue date, whichever comes first.

Note: Authority cited:

Adopt Section 64808.20 to read as follows:

§64808.20 Reciprocity Accreditation.

- (a) Another state or federal agency's environmental laboratory accreditation program shall be recognized for the purposes of reciprocity if the program's requirements related to proficiency testing, on-site assessments, quality assurance, laboratory facilities and equipment, test methods, and personnel are at least as stringent as State Board accreditation requirements.
- (b) Where reciprocity conditions exist, a laboratory applying for accreditation by reciprocity shall:
 - (1) Submit a completed application package in accordance with Section 64802.05;
 - (2) Comply with management and technical requirements, in accordance with Section 64802.10; and
 - (3) Pay the required fees, in accordance with Section 64802.30.
- (c) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by its primary accreditation body, it shall notify the State Board within 10 days of the suspension or revocation and its State Board certificate shall be automatically suspended or revoked as of the effective date of the action taken by the primary accreditation body.
- (d) If a reciprocity agreement with another state or federal agency is revoked, any certificate issued by the State Board to an affected laboratory shall be valid until the certificate expiration date.
- (e) A laboratory accredited under reciprocity may be subject to an on-site assessment. When the State Board conducts an on-site assessment for an out-of-state laboratory, the laboratory shall reimburse the State Board for all per diem and travel expenses incurred.

Note: Authority cited:

Amend Title of Article 4.

Article 4. ~~Site Visits~~ Types of Laboratories.

Repeal Section 64807

~~§64807. Site Visits.~~

~~(a) Site visits shall be conducted by the Department to verify information contained in a laboratory's application for certification or when a laboratory requests the addition of one or more Subgroups within a Field of Testing. During the site visit, the Department shall verify the following:~~

~~(1) the laboratory uses only the analytical test methods identified in Section 64811 for each Subgroup within a Field of Testing for which the laboratory is seeking certification;~~

~~(2) the laboratory's instrumentation and equipment meet the requirements of Section 64813;~~

~~(3) the laboratory's quality assurance and quality control procedures meet the requirements of Section 64815; and~~

~~(4) the information contained in the application.~~

~~(b) Within 30 days of completion of a site visit, the Department shall notify a laboratory, in writing, of its deficiencies, if any, in complying with the requirements of (a)(1) through (a)(4) above. No laboratory shall be issued a certificate in any Subgroup within any Field of Testing applied for unless it has corrected all deficiencies noted, and has forwarded to the Department a statement, in writing, of all corrective actions taken. The statement of corrective actions shall be received by the Department within the time frame established in the Department's notice of deficiencies. If in a subsequent site visit the Department determines that the laboratory failed to take any of the corrective action(s) specified in the laboratory's statement, citation(s) as specified under the authority of Health and Safety Code, Section 1021, may be issued.~~

~~(c) A site visit shall be conducted within 6 months from the date of receipt by the Department of a laboratory's application. If a site visit is not conducted within this time period and the delay is not a result of Department error or procedure, certification shall be denied pursuant to Section 64803(a)(2).~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.
Reference: Sections 1015, 1018 and 1021, Health and Safety Code.~~

Adopt Section 64810.00 to read as follows:

§64810.00. Stationary Laboratory.

(a) A laboratory may apply for accreditation of a stationary laboratory in accordance with Section 64802.05, provided that the stationary laboratory:

(1) Is permanent and non-movable; and

(2) May include fixed-in-place vehicles.

Note: Authority cited:

Adopt Section 64810.05 to read as follows:

§64810.05 Auxiliary Laboratory.

- (a) A laboratory may apply for a accreditation of an auxiliary laboratory in accordance with Section 64802.05, provided that each auxiliary laboratory:
- (1) Is operated by the owner of the primary laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination;
 - (2) Performs analyses in one or more of the same Field(s) of Testing and Unit(s) of Accreditation as the primary laboratory;
 - (3) Is under the supervision of the same technical manager;
 - (4) Receives samples only from, and reports raw analytical data only to, the primary laboratory for its generation of the final report;
 - (5) Is located such that transport of samples to the auxiliary laboratory does not affect the quality of the analytical results; and
 - (6) Is included in the primary laboratory's quality manual.
- (b) A laboratory may combine a stationary and auxiliary laboratory under a single accreditation, provided that each auxiliary laboratory complies with subsection (a).

Note: Authority cited:

Adopt Section 64810.10 to read as follows:

§64810.10 Mobile Laboratory.

- (a) A laboratory may apply for accreditation of a mobile laboratory in accordance with Section 64802.05, provided that each mobile laboratory:
- (1) Is a portable, enclosed structure (such as vehicle, vessel, aircraft, or trailer); and
 - (2) Is designed and equipped with necessary and appropriate accommodation and environmental conditions for the purpose of transporting and using laboratory equipment to perform analysis in the Field(s) of Accreditation for which accreditation is requested.
- (b) A laboratory may combine a stationary and mobile laboratory under a single accreditation, provided that each mobile laboratory:
- (1) Is operated by the owner of the primary laboratory;
 - (2) Performs analyses in one or more of the same Field(s) of Testing and Unit(s) of Accreditation as the primary laboratory;
 - (3) Is under the supervision of the same technical manager;
 - (4) Reports raw analytical data only to the primary laboratory for its generation of the final report; and
 - (5) Is included in the primary laboratory quality manual.

Note: Authority cited:

Amend Title of Article 5.

Article 5. ~~Performance Evaluation Testing Process~~ Laboratory Personnel and Equipment.

Repeal Section 64809

~~§64809. Performance Evaluation Testing.~~

~~(a) No laboratory shall be certified to perform analyses in any Subgroup of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of performance evaluation sample study set(s) (where performance evaluation sample study set(s) exist) in each Subgroup within each Field of Testing for which certification is requested, and the results for the testing of the study set are in agreement with the criteria established below:~~

~~(1) within the 99% confidence limit of the mean computed by the Department for the collection of results received for the performance evaluation sample set for the following Subgroups: detection of total coliform or fecal coliform organisms in wastewater by Multiple Tube Fermentation techniques; detection of total coliform or fecal coliform organisms in wastewater by Membrane Filter techniques; Heterotrophic Plate Count techniques; Fecal streptococci and Enterococci by Multiple Tube Fermentation techniques; Fecal streptococci and Enterococci by Membrane Filter techniques of Field of Testing 1; all Subgroups in Fields of Testing 6, 9, 10, 12, 13, 16, 17, 18, and 19;~~

~~(2) positive/negative, present/absent, above/below, or other similar discrete response when the only result possible from a test is a discrete response for the following Subgroups in Field of Testing 1: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Multiple Tube Fermentation techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Membrane Filter techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by use of Clark's Presence/Absence medium; detection of both total coliforms and Escherichia coli (E. coli) organisms in drinking water by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside-4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) techniques;~~

~~(3) for all Subgroups in Field of Testing 8: within the 99% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set, or within the 95th percentile of a distribution of non-normal values. The choice determined by the Department through the application of standard tests that determine the normalcy of data;~~

~~(4) within the 95% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set for the following Subgroups: alkalinity, calcium, chloride, corrosivity, hardness, magnesium, MBAS, sodium, sulfate, total filterable residue and conductivity, iron (colorimetric methods only), manganese (colorimetric methods only), and ortho phosphate in Field of Testing 2; asbestos in Field of Testing 3;~~

~~(5) within a given percentage of a known or true value for the following Subgroups: cyanide, fluoride, nitrate and nitrite in Field of Testing 2; all Subgroups in Field of Testing 3, except asbestos; all Subgroups in Fields of Testing 4, 5, 20, 21, and 22.~~

~~(b) Each performance evaluation sample study set shall state the method of evaluation that shall be utilized to score results for that performance evaluation sample study set, and which requirements identified in (a) above, or (c) below must be met by the laboratory.~~

~~(c) If a performance evaluation sample study set contains one or more analytes that may be analyzed by a single test method that the Department recognizes and certifies as a Subgroup of a Field of Testing, the results shall meet one of the following:~~

~~(1) when 6 or fewer analytes are in the performance evaluation sample study set, all analytes are within the stated acceptance limits; or~~

~~(2) when more than 6 analytes are in the performance evaluation sample study set, eighty-five point zero percent (85.0%) of the analytes are within the stated acceptance limits.~~

~~(d) If a laboratory fails to submit results for the analysis of performance evaluation sample study sets, which meet the above requirements, the laboratory may, within 30 days, request that it be given a second, successive attempt to submit such results. Failure of a laboratory to submit results for the analysis of performance evaluation sample study sets meeting the requirements of (a) or (c) within 6 months from the date of receipt by the Department of the laboratory's application for certification, or of its request for the addition of one or more Subgroups within a Field(s) of Testing shall result in the denial of the application or request.~~

~~(e) With the exception of Field of Testing 6, a certified laboratory shall, within 12 months from the date of certification, participate in at least one performance evaluation sample study set (where performance evaluation sample study set(s) exist) for each Subgroup within each Field of Testing as identified in Section 64823 for which certification is held. If the results from the study do not meet the requirements of (a) or (c), the laboratory shall be provided a second, successive attempt to submit such results. Irrespective of whether a second, successive attempt is provided, results meeting the requirements of (a) or (c) must be submitted by a certified laboratory to the Department at least 90 days prior to the expiration of its certificate or the laboratory's certificate may be restricted~~

~~under Health and Safety Code, Section 1015(c).~~

~~(f) Laboratories holding certification in any Subgroup within Field of Testing 6 shall participate in all available performance evaluation test samples provided through the Environmental Protection Agency's Environmental Monitoring and Support Laboratory, Las Vegas inter-comparison cross check and performance evaluation studies. The laboratory must successfully complete a minimum of two inter-comparison cross check studies and one performance evaluation study each annual period from the date of certification. Failure to do so may be used by the Department as grounds for restricting the laboratory's certificate under Health and Safety Code, Section 1015(c).~~

~~(g) Laboratories seeking or holding certification in any Subgroup within Field of Testing 11 are exempt from compliance with the requirements of Health and Safety Code, Section 1015(b)(1).~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1015, 1017 and 1019, Health and Safety Code.~~

Adopt Section 64812.00 to read as follows:

§64812.00 Laboratory Personnel.

- (a) A laboratory shall designate a technical manager. Except as provided in Subsections (b) and/or (c), the technical manager shall have at a minimum:
- (1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science; and
 - (2) Three years' experience in the analysis of chemical, biological, or microbiological samples, prior to being designated technical manager, subject to the following allowances:
 - (A) A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science may be substituted for one year of the required experience;
 - (B) A doctorate in chemistry, biochemistry, environmental, sanitary or chemical engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.
- (b) In lieu of meeting the requirements specified in Subsection (a), a technical manager employed by a laboratory owned by a public drinking water or wastewater utility shall have an Analyst/Water Quality Analyst Certificate from the California Water Environment Association (CWEA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA), in accordance with Table 64814, as follows:
- (1) A technical manager shall have, or obtain within one year of assuming the position, the highest certificate grade required for the performance of any Field(s) of Accreditation for which the laboratory is accredited.

Table 64814
Minimum Personnel Certification

<u>Fields of Accreditation (FoAs)</u>	<u>Minimum Certificate Grade</u>	<u>UoAs Allowed</u>
TBD	I	All
TBD	I	Alkalinity, Hardness, Total Filterable Residue, Conductivity, Chloride
TBD	II	Acidity, BOD, COD, Chlorine Residual, DO, pH, Turbidity, Residues
TBD	III	All
TBD	III	All, except those using ICP-MS
TBD	III	All, except those using GC-MS or LC-MS

- (c) The following shall be exempt from meeting Subsections (a) and (b):
- (1) A technical manager who was employed by an environmental testing laboratory at the time that the laboratory was accredited, provided that the accreditation date was on or before December 31, 1994; and
 - (2) A director of a public health laboratory, pursuant to Health and Safety Code Sections 101150 and 101160.
- (d) The technical manager, and/or his/her designee, shall comply with 2016 TNI Standard, Volume 1, Module 2, Section 4.1.7.2 (with the exception of part [f]), and 4.2.6.
- (e) The technical manager shall assume the position of, or shall designate another person as, the technical personnel responsible for the use of each sophisticated laboratory instrument in the laboratory.
- (f) If a technical manager is absent for a period of time exceeding 15 consecutive calendar days, a person meeting the qualifications of the technical manager shall be designated to serve as a temporary technical manager.
- (1) If the technical manager is absent for a period of time exceeding 35 consecutive calendar days the State Board shall be notified in writing.
- (g) The quality manager, and/or his/her designee, shall comply with 2016 TNI Standard, Volume 1, Module 2, Section 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2 and 4.14.1.
- (h) Technical personnel shall meet the education and experience requirements decided by laboratory management in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 5.2.
- (i) If a laboratory chooses to delay implementation of 2016 TNI Standard, Volume 1, the technical manager shall be responsible for:
- (1) The proficiency of all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and

- (2) Supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities; and
- (3) The accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.

Note: Authority cited:

Adopt Section 64812.05 to read as follows:

§64812.05 Laboratory Equipment.

- (a) A laboratory shall dispose of chemical wastes in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for Management of Hazardous Wastes, State of California, Department of Health Services.
- (b) A laboratory shall notify the State Board when there is a change in major instrumentation in accordance with Section 64814.00(d).
- (c) If a laboratory chooses to delay implementation of 2016 TNI Standard, Volume 1, the laboratory shall be arranged and operated so that:
 - (1) Utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Subgroup within each Field(s) of Testing for which the laboratory is certified;
 - (2) Ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond establish quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual;
 - (3) The design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;
 - (4) The storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations;
 - (5) Each piece of laboratory equipment meets all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory;
 - (6) Each piece of laboratory equipment is operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment; and
 - (7) Records are kept of all operational and maintenance activities associated with the operation of laboratory equipment.

Note: Authority cited:

Amend Title of Article 6.

Article 6. ~~Required Test Methods~~ Notifications/Reporting/Record Retention and Sale of Ownership.

Repeal Section 64811

~~§64811. Test Methods.~~

~~(a) Laboratories certified for any Subgroup within Fields of Testing 1 through 6, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 141 as amended July 17, 1992, 57 Federal Register 31776.~~

~~(b) Laboratories certified for any Subgroup within Fields of Testing 9 through 14, as identified in Section 64823, shall employ those methods found in Article 5, Section 66260.11, Title 22, California Code of Regulations.~~

~~(c) Laboratories certified for any Subgroup within Fields of Testing 8 or 16 through 19, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 136, amended September 11, 1992, 57 Federal Register 41830, or methods stated in any permit issued by a California Regional Water Quality Control Board. If no method is stated in the permit and there is no method cited for the substance in Part 136, the laboratory is to seek approval for the use of the method from the Regional Board issuing the permit.~~

~~(d) Laboratories certified for any Subgroup within Fields of Testing 20, 21 or 22, as identified in Section 64823, shall develop and employ analytical confirmation procedures for the verification of pesticide identification and quantification.~~

~~(e) Laboratories certified in any Subgroup within Field of Testing 7, as identified in Section 64823, shall employ those methods found in either "Recommended Procedures for the Examination of Sea Water and Shellfish", 4th edition, 1970, American Public Health Association (APHA); or "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th edition, 1984, AOAC, Arlington, Virginia. Laboratories certified in any Subgroup within Field of Testing 15, as identified in Section 64823, shall employ methods which were submitted to the Department at time of application for certification, or at time of request to add a Subgroup within a Field of Testing and which have been approved by the Department for use in the laboratory.~~

~~(f) Laboratories may substitute alternate test methods for those allowed by (a) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process, or shall obtain a waiver from the Environmental Laboratory Accreditation Program (ELAP), prior to implementing any substitution. ELAP may grant a waiver when a State Maximum Contaminant Level (MCL) is more stringent than a federal MCL or no State MCL exists and when ELAP determines that the test method the laboratory proposes to use is one for which that laboratory was previously ELAP certified. A waiver shall be valid until a~~

~~new State MCL is adopted for the analyte being detected by the method.~~

~~(g) Laboratories may substitute alternate test methods for those allowed by (b) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the California Environmental Protection Agency, Hazardous Materials Laboratory, Berkeley, California prior to implementing any substitutions.~~

~~(h) Laboratories may substitute alternate test methods for those allowed by (c) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process prior to implementing any substitution.~~

~~(i) Laboratories seeking certification for the subgroups consisting of fecal coliform or Escherichia coli (E. coli) organism technics, must also obtain, or hold, certification for the subgroups consisting of the same technic for total coliform organisms.~~

~~(j) To gain certification for individual radioactive elements or isotopes, except for uranium by fluorimetric technics, a laboratory shall obtain certification for gross alpha and beta radiation testing.~~

~~(k) A laboratory may seek certification, or hold certification for Field of Testing 11 without seeking or holding certification in Fields of Testing 10, 12, or 13. However, the laboratory shall submit all resulting preparations from the use of any of the subgroup members of Field of Testing 11 to a laboratory certified for Fields of Testing 10, 12, or 13.~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1012, 1017 and 28503, Health and Safety Code; Section 12901, Title 22, California Code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.~~

Adopt Section 64814.00 to read as follows:

§64814.00 Notification, Reporting, and Records Retention.

- (a) A laboratory shall comply with all requirements of state or federal regulatory agencies including, but not limited to, notification and reporting requirements.
- (b) Laboratories accredited to perform analysis on drinking water samples shall conform to the following notification and reporting requirements:
 - (1) A laboratory shall notify a water supplier's designated contact person as soon as possible following approval of sample results, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:
 - (A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed;

- (B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b); or
- (C) A nitrate sample exceeds the MCL.
- (2) A laboratory shall notify a water supplier's designated contact person as soon as possible following approval of sample results, but within 48 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:
 - (A) A perchlorate sample result exceeds the MCL; or
 - (B) A chlorine dioxide sample result that exceeds the maximum residual disinfectant level (MRDL).
- (3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, in accordance with subsection (b)(1) of this Section, or 48 hours in accordance with subsection (b)(2) of this Section, the laboratory shall immediately notify the State Board Division of Drinking Water and provide a written record of the time and method of attempted contacts.
- (4) With regard to notifying a water supplier's designated contact in subsection (b)(1) and subsection (b)(2) of this Section:
 - (A) "Approval" during the 24-hour period of subsection (b)(1) of this Section and the 48-hour period of subsection (b)(2) of this Section refers to the approval of the results by the laboratory's technical manager or designee, as set forth in the laboratory's quality manual.
 - (B) If a laboratory subcontracts an analysis to a subcontractor laboratory, unless the subcontractor provides the required notification pursuant to subsection (b)(1) of this Section or subsection (b)(2) of this Section, the subcontracting laboratory shall be responsible for providing the required notification pursuant to subsection (b)(1) of this Section or subsection (b)(2) of this Section.
- (5) Whenever a laboratory agrees to a request by a water supplier to invalidate a sample due to laboratory accident or error, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), the laboratory shall provide the supplier with:
 - (A) A letter from the laboratory technical manager to the water supplier agreeing to the invalidation request;
 - (B) Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;
 - (C) Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question;
 - (D) Copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and
 - (E) A report of the root cause of the failure and corrective actions taken in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 4.11 and Section 4.12.
- (6) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of

Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the State Board Division of Drinking Water.

- (7) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001, or as defined in the Environmental Information Exchange Network's Electronic Drinking Water Report Version 3.0 (eDWR V3.0), or by means of Web services, Templates or On-Line Web forms as directed and approved by the State Board Division of Drinking Water, by the 10th day of the month following the month in which the analyses were completed.
 - (8) All analytical results conducted pursuant to Title 22, California Code of Regulations, Division 4, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors, and Chapter 17.5, Lead and Copper, or other required monitoring shall be reported directly to the State Board Division of Drinking Water by the 10th day of the month following the month in which the analyses were completed. In the event that the State Board Division of Drinking Water is not able to accept those results for specific analytes electronically as set forth in subsection (b)(7) of this Section, results shall be submitted on paper or hard copy, or as otherwise directed by the State Board Division of Drinking Water.
- (c) When there is a change of technical manager and/or quality manager the laboratory shall:
- (1) Submit notification on forms prescribed by the State Board that includes, at a minimum:
 - (A) Name of the laboratory;
 - (B) Certificate number of the laboratory;
 - (C) Address of the laboratory;
 - (D) Name(s) of existing or terminated technical manager and/or quality manager;
 - (E) Name(s) of new technical manager and/or quality manager;
 - (F) Qualifications of new technical manager and/or quality manager in accordance with Section 64812.05; and
 - (G) Signature of the laboratory owner, owner's agent, or officer, and date signed;
- (d) When there is a change of sophisticated instrumentation the laboratory shall:
- (1) Submit notification on forms prescribed by the State Board that includes, but is not limited to:
 - (A) Name of the laboratory;
 - (B) Certificate number of the laboratory;
 - (C) Address of the laboratory; and

- (D) Documentation identifying the new instrumentation.
 - (2) Update any portion of the quality manual that differs because of the change of instrumentation;
 - (3) Update any portion of Standard Operating Procedure(s) that differ because of the change of instrumentation;
 - (4) Where applicable, comply with:
 - (A) 2016 TNI Standard, Volume 1, Module 3 through 7; or
 - (B) If a laboratory chooses to delay implementation of 2016 TNI Standard, Volume 1, the laboratory shall comply with Section 64812.05(c).
 - (5) Achieve acceptable scores in a Proficiency Testing study for any Unit(s) of Accreditation affected by the change of instrumentation, where Proficiency Testing studies exist; and
 - (6) Retain all records necessary for the State Board to determine compliance with subsection (d) for a minimum of 5 years.
- (e) A laboratory shall comply with reporting requirements in accordance with 2016 TNI Standard Volume 1, Section 5.10.
- (f) A laboratory shall report to its clients in accordance with the request for analysis, the full and complete results of all detected contaminants and pollutants from the analyses of the sample or components thereof.
- (g) Laboratories accredited for the analysis of pesticide residue in food shall verify the identity and quantity of a pesticide residue before reporting the results.
- (h) When a laboratory subcontracts work, the subcontracting laboratory shall comply with 2016 TNI Standard, Volume 1, Module 2, Section 4.5 and the subcontractor shall be accredited by the State Board in the Field(s) of Testing and/or Unit(s) of Accreditation for the tests to be performed.
- (i) Each laboratory shall establish and maintain comprehensive records in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 4.13.

Note: Authority cited:

Adopt Section 64814.05 to read as follows:

§64814.05 Sale or Transfer of Ownership.

- (a) Whenever the ownership of a laboratory has been sold or otherwise transferred, the new owner may apply to operate under the laboratory's existing certificate for either 90 days or until its expiration date as provided for in Health and Safety Code section 100845 subdivisions (b)(1) and (c), respectively.

- (b) The request to operate under the existing State Board certificate shall be granted when the following have occurred:
- (1) The new owner has submitted to the State Board within 30 days after the effective date of the laboratory ownership change a written request to retain the certificate;
 - (2) The laboratory has provided the following in writing to the State Board:
 - (A) Name(s) of the new owner(s) and the owner(s) designee;
 - (B) Effective date of the change of ownership;
 - (C) Final date requested for extension of accreditation;
 - (D) Name(s) of current technical manager and quality manager, or name(s) of technical manager and quality manager who quit, or were terminated and replaced as of the effective date of the ownership change; and the name(s) of technical manager and quality manager hired as replacements;
 - (E) Qualifications of personnel, addressing the requirements in Section 64812.00 for technical manager and quality manager;
 - (F) Statement that the new owner will operate pursuant to the laboratory's existing certificate and will not change anything in the quality manual without requesting and obtaining written approval from the State Board;
 - (G) Statement that the new owner will retain all records and data of analyses performed by the previous owner for a minimum of five (5) years;
 - (H) Statement that the new owner will comply with all applicable laws and regulations; and
 - (I) Signature of one or more of the new owner(s), or their agents.
 - (3) If changes to the laboratory are made that may affect adversely the quality of the analysis in any Field(s) of Accreditation, the laboratory shall submit Proficiency Testing report(s) with acceptable scores for any Unit(s) of Accreditation affected by the change, where Proficiency Testing studies exist;
 - (4) If the State Board at its discretion has conducted an on-site assessment, the laboratory has responded to any cited deviations and received the State Board's approval of the response to any cited deviations.
- (c) The laboratory under new ownership shall have its accreditation revoked as of the effective date of the ownership change if:
- (1) It does not comply with the requirements in Section 64814.05(b);
 - (2) If the new owner relocates the laboratory without State Board approval; or
 - (3) If more than half the laboratory's technical staff either quit or are terminated and replaced by the new owner upon assuming ownership.
- (d) The laboratory under new ownership shall be subject to having its certificate revoked upon State Board notification if an on-site assessment indicates inconsistencies with the information provided pursuant to Section 64814.05(b).

Note: Authority cited:

Amend Title of Article 7.

Article 7. ~~Laboratory and Equipment~~ Reasons for Denial, Suspension, or Revocation.

Repeal Section 64813

~~§64813. Laboratory and Equipment.~~

~~(a) A laboratory shall be arranged and operated so that:~~

~~(1) utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Subgroup within each Field(s) of Testing for which the laboratory is certified;~~

~~(2) ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond establish quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual;~~

~~(3) the design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;~~

~~(4) the storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations; and~~

~~(5) the disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes, State of California, Department of Health Services.~~

~~(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.~~

~~(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment.~~

~~(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.
Reference: Section 1012, Health and Safety Code; California Code of Regulations, Title 8; and Title 22, Division 4, Chapter 30, California Code of Regulations.~~

Adopt Section 64816 to read as follows:

§64816.00 Denying, Suspending, or Revoking Accreditation.

- (a) Reasons for denying a laboratory's application shall include, but are not limited to:
- (1) The laboratory fails to submit a completed application;
 - (2) The laboratory fails to pay fees;
 - (3) The laboratory fails to analyze and report acceptable scores in Proficiency Testing samples in accordance with 64802.20;
 - (4) The laboratory submits, as its own, proficiency testing sample results generated by another laboratory;
 - (5) The laboratory fails to pass required on-site assessment(s);
 - (6) The laboratory fails to respond to an On-Site Assessment Report with a Corrective Action Report in accordance with Section 64802.25;
 - (7) The laboratory fails to implement the corrective actions detailed in the Corrective Action Report within the required time frame;
 - (8) The laboratory fails to implement a quality system pursuant to Section 64802.10;
 - (9) The laboratory staff do not meet the personnel qualifications in accordance with Section 64812.00;
 - (10) The laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;
 - (11) The laboratory knowingly makes any false statement or representation pertinent to receiving accreditation;
 - (12) The laboratory knowingly makes any false statement or representation in any application, record, or other document; and/or
 - (13) The laboratory fails to comply with any other provision of these regulations.
- (b) Reasons for suspending or revoking accreditation shall include, but are not limited to:
- (1) If, during an on-site assessment, the State Board determines that suspension or revocation is necessary to protect public interest, safety or welfare;
 - (2) The laboratory fails to pay fees;
 - (3) The laboratory fails to complete proficiency testing studies as required;
 - (4) The laboratory fails to notify the State Board of changes in key accreditation criteria referenced in Section 64808.10(c)(d)(e) and (g);
 - (5) The laboratory fails to maintain a quality system pursuant to Section 64802.10;
 - (6) The laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;
 - (7) The laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;
 - (8) The laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;
 - (9) The laboratory fails to pass an on-site assessment;
 - (10) The laboratory fails to respond to an On-Site Assessment Report with a Corrective Action Report as required;

- (11) The laboratory fails to implement the corrective actions detailed in the Corrective Action Report within the required time frame;
 - (12) The laboratory knowingly makes any false statement or representation in any application, record, or other document; and/or
 - (13) The laboratory fails to comply with any other provision of these regulations.
- (c) If a laboratory's accreditation for a Field(s) of Accreditation and/or Unit(s) of Accreditation has been suspended, the laboratory shall cease all testing of samples for regulatory purposes for the Field(s) of Accreditation and or/ Unit(s) of Accreditation that were suspended.
- (d) If a laboratory's accreditation has been revoked, the laboratory shall:
- (1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, or their materials that contain reference to their past accreditation status;
 - (2) Return its original State Board certificate to the State Board;
 - (3) Cease all testing of samples for regulatory purposes;
 - (4) Notify all California regulatory clients of its revocation status within 3 days of receiving notice of revocation from the State Board;
 - (5) Provide the State Board with a list of regulatory clients affected by the revocation; and
 - (6) Discontinue use of subcontracting agreements with other State Board accredited laboratories within 7 days of receiving notice of revocation from the State Board.
- (e)

Note: Authority cited:

Repeal Article 8.

~~Article 8. Quality Assurance Documents.~~

~~§64815 Quality Assurance.~~

~~(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.~~

~~(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration~~

~~procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.~~

~~(c) The Laboratory Director shall review, and amend if necessary, the quality assurance program and quality assurance program manual at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.~~

~~(d) A laboratory shall maintain records of the implementation of its quality assurance program, and provide these records upon request of the Department. Records shall be maintained for a minimum of three years.~~

~~(e) This section shall become inoperative January 1, 2022.~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Section 1012, Health and Safety Code.~~

Repeal Article 9.

~~Article 9. Laboratory Personnel.~~

~~§ 64817. Laboratory Personnel.~~

~~(a) Each laboratory shall designate a Laboratory Director. Except as provided in (b) below, no person shall be designated as a Laboratory Director unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science.~~

~~(2) Has at least three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples. The experience requirement shall be satisfied from relevant work experience prior to the person having obtained the position of Laboratory Director. A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public hearing engineering, natural or physical science may be substituted for one year of the required experience. A doctorate in chemistry, biochemistry, environmental, sanitary or public hearing engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.~~

~~(b) Laboratory Directors of utility-owned water or wastewater treatment plant laboratories performing any of the analyses required under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Laboratory Director by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

Fields of Testing	Minimum Certificate	Grade Required
1, 2 [FNa1] and 16 [FNaa1]	_____	I
1, 2, 8 and 16	_____	II
3, 5, 17 and 19 plus those allowed for a grade II	_____	III
4, 6, and 18 plus those allowed for a grade III	_____	IV

~~[FNa1] Limited to testing for: alkalinity, chloride, hardness, total filterable residue, and conductivity.~~

~~[FNa2] Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, nonfilterable residue, settleable residue, volatile residue, specific conductance, and turbidity.~~

~~(c) All Laboratory Directors of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (a) or (b) above.~~

~~(d) A Laboratory Director shall be responsible for:~~

~~(1) all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and~~

~~(2) supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as Principle Analysts; and~~

~~(3) the accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.~~

~~(e) If, for any reason, a Laboratory Director leaves and is not replaced within 15 days by a person meeting the requirements specified in (a) or (b), whichever applies, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies the Department, pursuant to Section 1014(d) of the Health and Safety Code, describing the qualifications of the temporary director and receives written confirmation from the Department. An additional~~

~~extension of no more than ninety days beyond the original 90-day period may be granted by the Department, provided the laboratory can document that its good-faith efforts to recruit a qualified director were unsuccessful for reason beyond its control.~~

~~(f) A Laboratory Director shall assume the position of, or shall designate another person as Principal Analyst whenever there is use of a sophisticated laboratory instrument as defined in Section 64801(k). No person shall be a Principal Analyst for a laboratory unless he or she is:~~

~~(1) the user of the sophisticated laboratory instrument; or~~

~~(2) the supervisor of the users of the sophisticated laboratory instrument.~~

~~(g) Except as provided in (h) below, no person shall be a Principal Analyst unless he or she meets the following educational and experience requirements:~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or~~

~~(2) Possesses a certification of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the Principal Analyst; and~~

~~(3) Has at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, or food. This experience requirement must be satisfied from experience gained prior to obtaining the position of Principal Analyst.~~

~~(h) Principal Analysts of utility-owned water or wastewater treatment plant laboratories performing any analyses under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Principal Analyst by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

~~_____ Minimum~~

~~_____ Certificate _____~~

~~Fields of Testing _____ Grade Required~~

~~1, 2 and 16 _____ I~~

~~8 plus those allowed for~~

~~a Grade I _____ II~~

~~3, 5, 17 and 19 plus those~~

~~allowed for a grade II _____ III~~

~~4, 6, and 18 plus those
allowed for a grade III—IV~~

~~-~~

~~(i) All Principal Analysts of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (g) or (h) above.~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1012, Health and Safety Code.~~

Repeal Article 10.

~~Article 10. Notification and Reporting.~~

~~§ 64819. Notification and Reporting.~~

~~(a) Laboratories certified for Field of Testing 1, 2, 3, 4, 5, or 6 shall conform to the following reporting and notification requirements.~~

~~(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.~~

~~(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:~~

~~(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.~~

~~(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).~~

~~(C) A nitrate sample exceeds the MCL.~~

~~(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.~~

~~(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines &~~

~~Restrictions dated April 2001 and Data Dictionary dated April 2001, by the 10th day of the month following the month in which the analyses were completed.~~

~~(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:~~

~~(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;~~

~~(B) complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;~~

~~(C) complete description of the error alleged to have invalidated the result(s);~~

~~(D) copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and~~

~~(E) any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.~~

~~(b) Laboratories certified for Fields of Testing 20, 21, or 22 shall verify the identity and quantity of a pesticide residue before reporting the results. The confirmation procedures must conform to those in Section 64811(d) of this Chapter.~~

~~(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) prepared by all other laboratories who are party to the agreement.~~

~~Note: Authority cited: Sections 100275, 100830, 100835 and 116375, Health and Safety Code. Reference: Sections 100825(b) and 100835, Health and Safety Code.~~

Repeal Article 11.

~~Article 11. Reciprocity Agreements.~~

~~§64821. Reciprocity Agreements.~~

~~(a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if the program requires:~~

~~(1) periodic analyses of performance evaluation samples by the participating laboratories with the frequency of submittal, the method of evaluation, and the~~

~~established acceptance limits at least equal to those established in Section 64809 of this Chapter;~~

~~(2) on-site evaluation of participating laboratories during which the laboratory is reviewed under criteria at least equal to that established in Section 64807 of this Chapter;~~

~~(3) standards for quality assurance, laboratory facilities, test methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64811, 64813, 64815, and 64817 of this Chapter.~~

~~(b) Where reciprocity exists, each laboratory seeking California certification shall submit:~~

~~(1) an application pursuant to Section 64805(a) of this Chapter;~~

~~(2) copies of the results evaluated, or scored, from the last performance evaluation sample testing conducted by the laboratory for the other program;~~

~~(3) copies of the last on-site evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;~~

~~(4) all applicable fees pursuant to Health and Safety Code, Section 1017(a); and~~

~~(5) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.~~

~~(c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.~~

~~(d) If a reciprocity agreement with another State, or U.S. government agency is revoked, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.~~

~~(e) No fees are waived where reciprocity exists.~~

~~(f) A laboratory certified under reciprocity may be visited or issued performance evaluation samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable performance evaluation sample costs, pursuant to Section 1017(f) or travel costs pursuant to Section 1017(b) of the Health and Safety Code shall be paid.~~

~~— Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1014 and 1017, Health and Safety Code.~~

Repeal Article 12.

Article 12. Subgroups for Fields of Testing

~~§ 64823. Fields of Testing.~~

~~(a) Field of Testing 1 consists of those methods whose purpose is to detect the presence of microorganisms in the determination of drinking water or wastewater quality and encompasses the following Subgroups: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Membrane Filter technics; Heterotrophic Plate Count technics; detection of both total coliforms and Escherichia coli (E. coli) organisms by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside – 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by use of Clark's Presence/Absence medium; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics, Fecal streptococci and Enterococci by Membrane Filter technics; detection of total coliforms and fecal coliforms other than for drinking water or wastewater quality.~~

~~(b) Field of Testing 2 consists of those analytes or methods whose purpose is to detect the presence of inorganic substances in the determination of drinking water quality and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technic; and encompasses the following Subgroups: alkalinity; calcium (titrimetric technics); chloride; corrosivity; fluoride; hardness (direct determination); magnesium (titrimetric technics); methylene blue active substances (MBAS); nitrate; nitrite; sodium (flame emission technics); sulfate; total filterable residue and conductivity; iron; manganese; orthophosphate; silica; cyanide; potassium (flame emission technics).~~

~~(c) Field of Testing 3 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of drinking water quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: arsenic; barium; cadmium; total chromium; copper; iron; lead; manganese; mercury; selenium; silver; zinc; aluminum; asbestos; antimony; beryllium; nickel; thallium; calcium; magnesium; sodium; potassium.~~

~~(d) Filed of Testing 4 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 524.2 for volatile organics; EPA method 501.3 for trihalomethanes; EPA method 525 for acid and base/neutral compounds; EPA method 513 for dioxins; EPA method 1613 for dioxins.~~

~~(e) Field of Testing 5 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 501.1 for trihalomethanes; EPA method 501.2 for trihalomethanes; EPA method 510 for total trihalomethanes; EPA~~

method 508 for chlorinated pesticides; EPA method 515.1 for chlorophenoxy herbicides; EPA method 502.1 for halogenated volatiles; EPA method 503.1 for aromatic volatiles; EPA method 502.2 for both halogenated and aromatic volatiles; EPA method 504 for EDB and DBCP; EPA method 505 for chlorinated pesticides and polychlorinated biphenyls; EPA method 507 for the haloacids; EPA method 531.1 for carbamates; EPA method 547 for glyphosate; EPA method 506 for adipates and phthalates; EPA method 508A for total polychlorinated biphenyls; EPA method 548 for endosulfan; EPA method 549 for diquat and paraquat; EPA method 550 for polycyclic aromatic hydrocarbons; EPA method 550.1 for polycyclic aromatic hydrocarbons; EPA method 551 for chlorination disinfection byproducts; EPA method 552 for haloacetic acids.

(f) Field of Testing 6 consists of those methods whose purpose is to detect the presence of radioactive substances in drinking water, wastewater, or hazardous wastes; and encompasses the following Subgroups: gross alpha and beta radiation; total radium; radium 226; uranium; radon 222; radioactive cesium; iodine 131; radioactive strontium; tritium; gamma emitting isotopes; gross alpha by coprecipitation; radium 228; radioactive iodine; gross alpha and beta radiation in hazardous wastes; alpha emitting radium isotopes in hazardous wastes; radium 228 in hazardous wastes.

(g) Field of Testing 7 consists of those methods whose purpose is to detect the presence of microbial contamination or toxins in the determination of shellfish meat quality and encompasses the following Subgroups: shellfish meat microbiology; paralytic shellfish poison (PSP) and other marine biotoxins; microbiology of shellfish growing waters.

(h) Field of Testing 8 consists of those methods whose purpose is to detect the presence of toxins in the determination of wastewater quality, or in hazardous wastes and encompasses the following Subgroups: hazardous waste testing pursuant to Title 22, California Code of Regulations, Section 66261.24(a)(6); wastewater testing according to Kopperdahl (1976) using freshwater fish; wastewater testing according to EPA/600/4-85/013 using freshwater and/or marine organisms; wastewater testing by EPA method 1000.0; wastewater testing by EPA method 1002.0; wastewater testing by EPA method 1003.0; wastewater testing by EPA method 1006; wastewater testing by EPA method 1007; wastewater testing by EPA method 1009; wastewater testing according to Anderson, et al. (1990) using Giant Kelp (*Macrocystis pyrifera*); wastewater testing according to Anderson, et al. (1990) using red abalone (*Haliotis rufescens*); wastewater testing according to Dinnel and Stober (1987) using purple sea urchin (*Strongylocentrotus purpuratus*); wastewater testing according to Dinnel and Stober (1987) using red sea urchin (*Strongylocentrotus franciscanus*); wastewater testing according to Dinnel and Stober (1987) using sand dollar (*Dendraster excentricus*); wastewater testing according to procedure E 724-89 (ASTM, 1989) using Pacific oyster (*Crassostrea gigas*); wastewater testing according to procedure E 724-89 (ASTM, 1989) using California Bay Mussel (*Mytilus edulis*); wastewater testing according to procedure E 1218-90 (ASTM, 1990) using an alga (*Skeletonema costatum*); wastewater testing according to EPA/600/4-90/027 using freshwater and/or marine organisms.

(i) Field of Testing 9 consists of those methods whose purpose is to detect physical

~~properties of hazardous wastes for regulatory purposes and encompasses the following Subgroups: ignitability; corrosivity by pH determination; corrosivity by corrosivity towards steel; reactivity.~~

~~(j) Field of Testing 10 consists of those methods whose purpose is to detect the presence of inorganic substances in hazardous waste samples and encompasses the following Subgroups: antimony; arsenic; barium; beryllium; cadmium; chromium, total; cobalt; copper; lead; mercury; molybdenum; nickel; selenium; silver, thallium; vanadium; zinc; chromium (VI); cyanide; fluoride; sulfide; total organic lead.~~

~~(k) Field of Testing 11 consists of those methods whose purpose is to prepare samples of hazardous wastes for further testing and encompasses the following Subgroups: California waste extraction test (WET); extraction procedure toxicity (EP TOX); toxicity characteristic leaching procedure (TCLP), all phases; TCLP, extraction of inorganics only; TCLP, extraction of semivolatile organics only; TCLP, extraction of volatile organics only.~~

~~(l) Field of Testing 12 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8240 for volatile compounds; EPA method 8250 for semivolatile compounds; EPA method 8270 for semivolatile compounds; EPA method 8280 for dioxins, EPA method 8290, EPA method 8260.~~

~~(m) Field of Testing 13 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8010 for halogenated volatiles; EPA method 8015 for nonhalogenated volatiles; EPA method 8020 for aromatic volatiles; EPA method 8030 for acrolein, acrylonitrile, acetonitrile; EPA method 8040 for phenols; EPA method 8060 for phthalate esters; EPA method 8080 for organochlorine pesticides or polychlorinated biphenyls; EPA method 8090 for nitroaromatics and cyclic ketones; EPA method 8100 for polynuclear aromatic hydrocarbon; EPA method 8130 for polynuclear aromatic hydrocarbons; EPA method 8120 for chlorinated hydrocarbons; EPA method 8140 for organophosphorus pesticides; EPA method 8150 for chlorinated herbicides; EPA method 632 for carbamates; total petroleum hydrocarbons – gasoline (LUFT manual); total petroleum hydrocarbons – diesel (LUFT manual); EPA method 8011; EPA method 8021; EPA method 8070; EPA method 8110; EPA method 8141; EPA method 8330; EPA method 8080 for PCBs only; EPA method 8080 for chlorinated pesticides only.~~

~~(n) Field of Testing 14 consists of those methods whose purpose is to detect the presence of asbestos for purposes of complying with the provisions of Title 22, California Code of Regulations, Section 66261.24(a)92)(A) and encompasses the following Subgroups: asbestos by polarized light microscopy.~~

~~(o) Field of Testing 15 shall be any method whose purpose is to detect the presence of any analyte found in the list of substances regulated by the California Safe Drinking~~

~~Water and Toxic Enforcement Act in drinking water, wastewater, hazardous wastes, and contaminated soils or sediments, but which method is not within any subgroup of any other Field of Testing cited in this section.~~

~~(p) Field of Testing 16 consists of those methods whose purpose is to detect the presence of inorganic substances, nutrients, physical or chemical demands, or physical properties in the determination of wastewater quality, and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technics and encompasses the following Subgroups: acidity; alkalinity (includes determination of bicarbonate, carbonate, & hydroxide); ammonia; biochemical oxygen demand (BOD); boron; bromide; calcium (titrimetric technics); carbonaceous biochemical oxygen demand (cBOD); chemical oxygen demand (COD); chloride; chlorine residual, total; cyanide; cyanide amenable to chlorination; fluoride; hardness (direct determination); kjeldahl nitrogen (includes determination of organic nitrogen); magnesium (titrimetric technics); nitrate; nitrite; oil and grease; organic carbon; oxygen, dissolved, pH; phenols; phosphate ortho; phosphorus, total; potassium (flame emission technics); residue, total; residue, filterable (total dissolved solids); residue, nonfilterable (total suspended solids); residue, settleable (settleable solids); residue, volatile; silica; sodium (flame emission technics); specific conductance; sulfate; sulfide (includes total and soluble); sulfite; surfactants (MBAs); tannin and lignin; turbidity; iron; manganese; total recoverable hydrocarbons by EPA method 418.1; total organic halides.~~

~~(q) Field of Testing 17 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of wastewater quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: aluminum; antimony; arsenic; barium; beryllium; cadmium; chromium (VI); chromium, total; cobalt; copper; gold; iridium; iron; lead; manganese; mercury; molybdenum; nickel, osmium; palladium; platinum; rhodium; ruthenium; selenium; silver; strontium; thallium; tin; titanium; vanadium; zinc; asbestos; calcium; magnesium; potassium; sodium.~~

~~(r) Field of Testing 18 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 624 for volatile organics; EPA method 625 for acid and base/neutral compounds; EPA method 1613 for dioxins; EPA method 1625 for dioxins; EPA method 613.~~

~~(s) Field of Testing 19 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 601 for halogenated volatiles; EPA method 602 for aromatic volatiles; EPA method 603 for acrolein, acrylonitrile, acetonitrile; EPA method 604 for phenols; EPA method 605 for benzidine; EPA method 606 for phthalate esters; EPA method 607 for nitrosoamines; EPA method 608 for organochlorine pesticides or polychlorinated biphenyls; EPA method 609 for~~

~~nitroaromatics and cyclic ketones; EPA method 610 for polynuclear aromatics; EPA method 612 for haloethers; EPA method 632 for carbamates; EPA method 619; EPA method 608 for PCBs only; EPA method 608 for chlorinated pesticides only.~~

~~(t) Field of Testing 20 consists of those methods whose purpose is to detect the presence of inorganic pesticide residues in raw agricultural or bulk processed food and encompasses the following Subgroups: pesticide residues in processed foods detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in raw commodities detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in dairy products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in feed products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics.~~

~~(u) Field of Testing 21 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: chromatographic/mass spectrophotometric methods in either processed foods; raw commodities; dairy products; feed products.~~

~~(v) Field of Testing 22 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: halogenated compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in feed products detected by either gas chromatography, high~~

~~pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics.~~

~~(w) Field of Testing 23 consists of the subgroup members appropriate to the Field of Testing stated by the laboratory, pursuant to Section 64805(b)(1).~~

~~—Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1012, 1013, 1015, 1017 and 1019, Health and Safety Code.~~

Repeal Article 13

~~Article 13. Trade Secrets.~~

~~§64825. Trade Secrets.~~

~~(a) If a laboratory identifies information provided to the Department as a trade secret, the Department shall not release such information unless:~~

~~(1) the release is authorized under state or federal law; and~~

~~(2) the Department has notified the laboratory of the impending release. Such notification shall be at least ten days prior to releasing any information identified as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1012 and 1013, Health and Safety Code; Section 6254.7(d), Government Code.~~

Repeal Article 14.

~~Article 14. Sale or Transfer of Ownership of a Laboratory.~~

~~§ 64827. Sale or Transfer of Ownership.~~

~~(a) A certificate shall be voided by operation of law if one or more of the following occurs.~~

~~(1) An original Owner fails to notify the Department, in writing, within 15 days after a change in ownership.~~

~~(2) A new Owner relocates the laboratory within 90 days of assuming ownership.~~

~~(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.~~

~~(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of any Subgroup within any Field of Testing.~~

~~(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information:~~

~~(1) The name(s) of the new Owner(s).~~

~~(2) The date of sale or transfer of ownership.~~

~~(3) The name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the person designated as the Laboratory Director.~~

~~(4) The names, education and laboratory related work experiences, as specified in Section 64817(g); or voluntary laboratory certificate grade as specified in Section 64817(h), of all persons who are designated as Principal Analysts.~~

~~(5) The names of all Principal Analysts who have quit, or were terminated and replaced; and the names of all Principal Analysts hired as replacements.~~

~~(6) A statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership.~~

~~(7) A statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership.~~

~~(8) The notice shall be signed by one or more of the new Owner(s), or their Agents.~~

~~(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.~~

~~(1) The certificate number and the laboratory name appearing on the certificate shall remain the same.~~

~~(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.~~

~~(d) To obtain the use of the certificate to its original expiration date, the new Owner shall request such use in writing, and the laboratory shall be subjected to, and pass the following, within the 90 days use period granted by the Department.~~

~~(1) A site visit in accordance with Section 64807; and~~

~~(2) Performance evaluation samples in accordance with Section 64809.~~

~~—Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.
Reference: Section 1014, Health and Safety Code.~~

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